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Award Number: W81XWH-09-2-0018

TITLE: Optical Quality, Threshold Target Identification, and Military Target Task Performance after Advanced Keratorefractive Surgery

PRINCIPAL INVESTIGATOR: Kraig Bower

CONTRACTING ORGANIZATION: Henry M. Jackson Foundation for the Advancement of Military Medicine
Rockville, MD 20652

REPORT DATE: May 2011

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
01-05-2011	Annual	1 MAY 2010 - 30 APR 2011

4. TITLE AND SUBTITLE
Optical Quality, Threshold Target Identification, and Military Target Task Performance after Advanced Keratorefractive Surgery

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-09-2-0018

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Henry M. Jackson Foundation for the Advancement of Military Medicine
Rockville, MD 20652

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The purpose of the present study is to investigate the effect of advanced refractive surgery on task performance in a military operational setting. In this prospective, randomized treatment trial we will enroll 224 nearsighted soldiers to undergo wavefront-guided (WFG) photorefractive keratectomy (PRK), WFG laser in situ keratomileusis (LASIK), wavefront optimized (WFO) PRK or WFO LASIK (56 in each group). Subjects will undergo extensive clinical and military visual performance testing pre- and postoperatively. Night Vision and Electronic Sensors Directorate (NVESD) performance prediction models (the Target Task Performance [TTP] metric) will analyze data derived from the contrast sensitivity function to predict whether there is a significant difference in either the range at which target identification can be made or the time a target can be detected. Military task performance will be further evaluated by the NVESD program (threshold target identification) in which tracked vehicle targets will be presented to observers at a sufficient distance to stress the eye response. The percentage of correctly identified stimuli will be plotted as a function of range to produce a psychometric function. Finally, night firing range performance will be determined before and after surgery. Study design will enable comparison to preoperative performance as well as comparisons between treatment groups.

15. SUBJECT TERMS
Military, Refractive Surgery, PRK, LASIK, Night Vision, Wavefront Optimized, Wavefront Guided, Visual Performance, Quality of Vision, Outcomes, Contrast Sensitivity

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
U	U	U	UU	29	**19b. TELEPHONE NUMBER** *(include area code)*

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INTRODUCTION

Visual performance is critical for the successful execution of many military tasks including target detection and identification. Although refractive surgery offers substantial benefits on the battlefield when compared to glasses, surgically induced higher order optical aberrations (HOA) may affect quality of vision in terms of contrast sensitivity, glare, haloes, and reduced night vision. Because most military operations occur in low light/low contrast setting, any further degradation of vision as a result of refractive surgery can adversely impact military task performance. Wavefront optimized (WFO) and wavefront guided (WFG) surgery aim to minimize HOA improve postoperative quality of vision. The purpose of the present study is to investigate the utility of these advanced refractive surgery technologies in the military. In a prospective, randomized treatment trial we will enroll 224 nearsighted soldiers to WFG photorefractive keratectomy (PRK), WFG LASIK, WFO PRK or WFO LASIK (56 in each group). This collaboration between the Center for Refractive Surgery at Walter Reed Army Medical Center (WRAMC), The National Naval Medical Center (NNMC), and the US Army Night Vision and Electronic Sensors Directorate (NVESD) will evaluate refractive surgery results in terms of subjective visual performance, objective optical quality, performance predication modeling, and military task performance. Human subjects will be seen only after approval by the WRAMC and NNMC Institutional Review Boards and the USAMRMC Human Research Protection Office.

BODY

With the 2005 Base Realignment and Closure Act Walter Reed Army Medical Center and the National Naval Medical Center in Bethesda will merge and form a new Walter Reed National Military Medical Center (WRNMMC). Construction is under way for a renovated North Campus in Bethesda and a new South Campus at Ft. Belvoir. As part of that realignment the Ophthalmology Services at the respective centers will combine to form an integrated ophthalmology service responsible to staff both hospitals, beginning in 2011.

In preparation for the BRAC, the new integrated ophthalmology service, and personnel changes, the principal investigator, along with the Walter Reed Center for Refractive Surgery research staff, determined that the following modifications would best serve the long term success of the research activities:

- In light of Dr. Bower's retirement from the Army, a modification was submitted requesting a change in WRAMC site PI from Dr. Bower to Dr. Mines.
- To address personnel changes, modifications requesting addition of the following personnel as associate investigators was submitted: Drs. Shaw, Logan, Stutzman, Pasternak, Sia, Trudo, and Mr. Peppers.
- To provide medical monitor coverage in anticipation for a scheduled absence at NNMC, a modification requesting WRAMC medical monitor cover NNMC was submitted.
- Due to the slower paced enrollment in the LASIK groups, a modification requesting continued enrollment in Phase II PRK patients was requested, while continuing enrollment of Phase I LASIK patients.

- To update the WRAMC consent form to the current DCI format and to address BRAC changes when enrolling patients, a modification requesting a change in WRAMC consent form to include BRAC transition verbiage and the combination of HIPAA and WRAMC consent form was submitted.

All of the aforementioned modifications have been approved by the WRAMC IRB. Some are still pending submission or approval to the NNMC IRB. The consent form modification will not be submitted to the NNMC IRB as the two sites will fall under a unified consent form upon closure of WRAMC.

A copy of the currently approved consent form, and approval letters for the modifications are attached as **Appendix 1** at the conclusion of this report.

Due to the BRAC, study surgeries have been discontinued as of 21 March 2011. This decision is in the best long-term interest of the study and will allow for already enrolled patients to complete their scheduled follow ups in a timely manner with minimal disruption, although it does place us significantly behind the original timeline outlined in the grant proposal. Nevertheless, we are now following treated patients and will begin recruiting patients in July and August in anticipation for Phase I LASIK and Phase II PRK enrollment and surgery post-BRAC.

In order to begin Phases II and III, the NVESD protocol required approval from the U.S. Army Medical Research and Material Command's IRB. The research staff at WRAMC was intimately involved in planning, preparing and developing the protocol. The NVESD received approval for testing in Phases II and III on 10 March 2011. To prepare for the first enrollments in Phase II, the research staff at WRAMC visited the night firing range at NVESD in December to coordinate firing procedures. Furthermore, Mr. Clifford Surrett Sr., the Night Firing Range supervisor, will provide tentative dates in September and October 2011 for preoperative and 6 week postoperative firing appointments by 1 June 2011.

As of the date of this report we have enrolled 28 WFO PRK, 28 WFG PRK, 10 WFO LASIK, and 11 WFG LASIK patients in Phase I of the study (2 WFO PRK disenrolled prior to treatment) with the following follow up rates: 1 Month (M)-100%, 3M-98% PRK, 100% LASIK, 6M-98% PRK,100% LASIK, 12M- 100% PRK, 100% LASIK.

Table 1: Summary of study phases:

The study will be conducted in three phases
Phase 1 (112 patients) - no additional NVESD testing (PRK group complete)
Phase 2 (56 patients) - NVESD target detection testing, (28 PRK, 28 LASIK)
Phase 3 (56 patients) - night firing range

The following adverse events were reported since the last annual report: In the first event, a sterile corneal infiltrate/ ulcer was discovered. This adverse event was not the result of the study, but

rather a recognized result of the surgery. There was no change in the risk/ benefit ratio, as corneal ulcers are recognized potential complications of refractive surgery. The final outcome will likely be good, as the ulcer is not in the visual axis. In the second event, the patient developed infectious keratitis, an unfortunate complication but one that is a recognized potential with all forms of keratorefractive surgery. The complication was not due to a breach of standard of care and was not due to participation in this study protocol. In a follow-up report based on the most recent eye exam, the patient's visual outcome was improved with resolution of the adverse event. In the last event, the patient had a traumatic dislocation of a LASIK flap which was not due to subject's participation in this study protocol. In a follow up report based on recent examination, the final visual outcome for this patient will likely be good. No changes in the protocol or the study consent form were recommended after any event as the risk of having complications after the LASIK and PRK procedures are included in the consent form and the risks of surgery are listed in a separate surgical consent form.

KEY RESEARCH ACCOMPLISHMENTS

- WRAMC IRB continuing review approval (X/X/XXX)
- NNMC IRB continuing review approval (//2010)
- Currently preparing for NNMC continuing review and audit scheduled for 3 June 2011.
- WRAMC and NNMC IRB approval of multiple modifications
- Initial NVESD IRB approval (3/10/2011)
- Cambridge system – obtained a back-up CB6 response box to eliminate down time caused by technical difficulties.
- Meeting with NFR's supervisor Clifford Surrett Sr.to plan and develop the NFR testing and coordinate patient flow. (12/13/2010).
- The COAS-HD wavefront aberrometer for wavefront measurements was returned to the manufacturer with ongoing problems. This system will no longer be used as part of Phase I of the study due to its inoperability. The manufacturer is in the process of final inspection before returning the COAS HD. No anticipated ship date has been provided.
- Two refractive research staff attending the Association for Research in Vision and Ophthalmology Annual meeting and the International Society for Imaging in the Eye conference to obtain up-to-date information on night vision and quality of vision research. A short synopsis on findings from the conference is attached as Appendix 2.

- Performed first WFO study treatments at WRAMC (4/26/2010) and first WFG study treatments at NNMC (4/29/2010).

- Submitted no-cost extension request to HMJ.

- Initiated budget reprogramming request at HMJ.

REPORTABLE OUTCOMES
None

CONCLUSION
None

REFERENCES
None
SUPPORTING DATA
None

APPENDICES
Appendix 1 WRAMC and NNMC modification approval letters
Appendix 2 Findings from ARVO meeting

DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WALTER REED HEALTH CARE SYSTEM
WASHINGTON, DC 20307-5001

REPLY TO
ATTENTION OF

MCHL-CI

22 November 2010

MEMORANDUM FOR LTC Michael Mines, Ophthalmology Service, Department of Surgery, Walter Reed Army Medical Center, Washington, DC 20307-5001

SUBJECT: Approval of Request for PI Change to IRB Net#20481-8/WU#08-6967: "Optical Quality, Threshold Target Identification, and Military Target Task Performance after Advanced Keratorefractive Surgery."

1. Your PI Change request was submitted in IRB Net on 8 September 2010, and complete documents were received on 13 September 2010. Materials provided demonstrated the proposed new principal investigator is qualified by training and experience. This request was reviewed and approved by expedited review procedures by MAJ Jessica Zaret, MC, Chief, Research Review Service, Department of Clinical Investigation on 22 November 2010 IAW 32 CFR 219.110 and will be reported to the IRB on 14 December 2010.

2. The stamped Consent Form/HIPAA Authorization that must be duplicated and used for enrolling new subjects will be issued with the approved IRB Net package 20481-8.

3. If you have any questions, please contact Daniel Rosen at (202) 782-7896.

ZARET.JESSICA.H.1162251992
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Date: 2010.11.22 08:23:33 -05'00'

Jessica Zaret
MAJ MC
Chief, Research Review Service
Department of Clinical Investigation
Walter Reed Army Medical Center

DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WALTER REED HEALTH CARE SYSTEM
WASHINGTON, DC 20307-5001

REPLY TO
ATTENTION OF

MCHL-CI (40-38a) 22 November 2010

MEMORANDUM FOR LTC Michael Mines, Ophthalmology Service, Department of Surgery, Walter Reed Army Medical Center, Washington, DC 20307-5001

Subject: Personnel change to IRBNET#20481-10 (WU#08-6967)

Per your request, LTC Kenneth Shaw has been added as an Associate Investigator to the WRAMC Protocol "Optical Quality, Threshold Target Identification, and Military Target Task Performance after Advanced Keratorefractive Surgery". LTC Shaw last completed the CITI Research Course on 24 August 2010 and is qualified to be an Investigator on this protocol performed through Walter Reed.

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Date: 2010.11.22 08:52:54 -05'00'

Jessica Zaret
MAJ MC
Chief, Research Review Service
Department of Clinical Investigation
Walter Reed Army Medical Center

DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WALTER REED HEALTH CARE SYSTEM
WASHINGTON, DC 20307-5001

REPLY TO
ATTENTION OF

MCHL-CI (40-38a) 12 January 2011

MEMORANDUM FOR LTC Michael Mines, Ophthalmology Service, Department of Surgery, Walter Reed Army Medical Center, Washington, DC 20307-5001

Subject: Personnel change to IRBNET#20481-13 (WU#08-6967)

Per your request, COL Richard Stutzman, MC, Dr. Joseph Pasternak, MD, Dr. Rose Kristine Sia, MD, Mr. Lamarr Peppers, and Dr. Lorie Logan, OD have been added as Associate Investigators to the WRAMC Protocol "Optical Quality, Threshold Target Identification, and Military Target Task Performance after Advanced Keratorefractive Surgery". COL Stuzman last completed the CITI Research Course on 24 June 2008 , Dr. Pasternak on 5 November 2010 , Dr. Sia on 9 October 2009, Mr. Peppers on 3 August 2007, and Dr. Logan on 15 August 2010 which qualifies them to be Investigators on protocols performed through Walter Reed.

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Jessica Zaret
MAJ MC
Chief, Research Review Service
Department of Clinical Investigation
Walter Reed Army Medical Center

DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WALTER REED HEALTH CARE SYSTEM
WASHINGTON, DC 20307-5001

REPLY TO
ATTENTION OF

MCHL-CI

DATE: January 12, 2011

TO: Michael Mines, MD
FROM: Jessica Zaret, MAJ MC, Chief, Research Review Services

STUDY TITLE: **[20481-12 & 20481-14]** Optical Quality, Threshold Target Identification, and Military Target Task Performance after Advanced Keratorefractive Surgery
REFERENCE #: 08-6967(3)
SUBMISSION TYPE: Amendment/Modification (**20481-12**) & Response/Follow-Up (**20481-14**)

ACTION: Response Required for **20481-12** & APPROVED for **20481-14**
APPROVAL DATE: January 11, 2011
EXPIRATION DATE: August 11, 2011
REVIEW TYPE: Full Committee Review for both **20481-12** & **20481-14**

1. Your memorandum was received by DCI and was reviewed by the WRAMC Institutional Review Board (IRB) on 14 Dec 2009

- with a response required.

The response was discussed by the WRAMC Institutional Review Board (IRB) on 11 Jan 2011 and the amendment was approved.

- No consent form changes were submitted in this amendment.
- No HIPAA changes were submitted in this amendment.

2. If your study has been approved for acceptance of loaned equipment or the provision of an (IND) drug/ Placebo, (IDE) device, supplies and/or gift or money or property, you must coordinate this requirement with Ms. Word, Research Administration Service, DCI, Building #6, Room 4009 at 782-7859. Only Pharmacy Service, not the principal investigator, is authorized to receive and dispense drugs.

3. The protocol was originally approved on August 12, 2008.

4. If you have any questions, please contact Kristin Beltz at 202 782-7848.

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Date: 2011.01.12 12:20:50 -05'00'

Chief, Research Review Service
Asst. Chief, Department of Clinical Investigation

"Electronic Signature Notice: In accordance with the "Government Paperwork Elimination Act" (GPEA) (Pub.L. 105-277; codified at 44 USC 3504); Federal and DOD applicable instructions, directives and regulations, documents have been electronically signed and authorized by all who have been required to do so. These signatures have the same effect as their paper-based counterparts. Verification is retained within our protected electronic records and audit trails."

DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WALTER REED HEALTH CARE SYSTEM
WASHINGTON, DC 20307-5001

REPLY TO
ATTENTION OF

MCHL-CI

DATE: 23 FEB 2011

TO: LTC Michael Mines, MC, USA
FROM: Kristin Beltz, MA, CIP, Research Review Service

STUDY TITLE: [20481-15] Optical Quality, Threshold Target Identification, and Military Target Task Performance after Advanced Keratorefractive Surgery
REFERENCE #: 08-6967(4)
SUBMISSION TYPE: Amendment/Modification

ACTION: APPROVED
APPROVAL DATE: 23 FEB 2011
EXPIRATION DATE: 11 AUG 2011
REVIEW TYPE: Administrative Review

1. Your memorandum was received by DCI and was reviewed and approved administratively with a minor change* by the undersigned by the authority of the Chief, RRS.

The approval of this amendment will be reported at the next meeting of the WRAMC Institutional Review Board (IRB) on 22 March 2011.

You may incorporate the changes indicated by this amendment upon receipt of this letter.

- **Enclosed is the approved revised consent form+HIPAA authorization that must be duplicated and used for enrolling the subjects.**
- **Also enclosed is the identical Word version of the stamped, approved, revised consent form +HIPAA in case it is needed in the future.**
- **In the next package that is submitted to DCI, please update the DMRN Research Project Coversheet with all CITI certificate dates for all personnel (in the "training" sections).**

* The following sentence was deleted from the consent form+HIPAA because it no longer applies: "A HIPAA authorization form for this study will be provided to you separately, and you will be asked to sign that form."

2. If you have any questions, please contact me at 202 782-7848.

E-Signed by BELTZ.KRISTIN.E.1158750410
VERIFY authenticity with ApproveIt

BELTZ.KRISTIN.E.1158750410

Clinical Research Coordinator

Research Review Service
Department of Clinical Investigation

"Electronic Signature Notice: In accordance with the "Government Paperwork Elimination Act" (GPEA) (Pub.L. 105-277; codified at 44 USC 3504); Federal and DOD applicable instructions, directives and regulations, documents have been electronically signed and authorized by all who have been required to do so. These signatures have the same effect as their paper-based counterparts. Verification is retained within our protected electronic records and audit trails."

WALTER REED ARMY MEDICAL CENTER
WASHINGTON, D.C

This Clinical Trial consent form is valid only if it contains the IRB stamped date.

Consent for Voluntary Participation in a Clinical Trial (a type of research study) Entitled: "Optical Quality, Threshold Target Identification, and Military Target Task Performance After Advanced Keratorefractive Surgery".

Principal Investigator: LTC Michael J. Mines, MC, Ophthalmology Service, Department of Surgery, phone (202) 782-0202.

Study Site: XX NNMC, XX WRAMC, XX FBCH, XX WRNMMC (after 15 September 2011)

1. INTRODUCTION OF THE STUDY

You are being asked to be in this research study because you are an active duty U.S. Army Soldier, age 21 or older, will be located in the national capital region for at least 1 year, and wear either glasses or contact lenses for either nearsightedness and/or astigmatism (unequal curvature of the eyeball). Your participation is voluntary. Refusal will not result in any penalty or loss of benefits to which you are otherwise entitled, nor will refusal have any affect on your military career status.

2. PURPOSE OF THE STUDY

The purpose of this research project is to evaluate the outcomes of visual performance in nighttime military settings before and after receiving wavefront guided or wavefront optimized laser assisted in situ keratomileusis (LASIK) or photorefractive keratectomy (PRK) surgery. Although daytime vision is often excellent following refractive surgery, there have been reports of night vision changes resulting from PRK and LASIK.

Studies have shown LASIK and PRK to be safe and effective in the treatment of nearsightedness, farsightedness and astigmatism (e.g. corneal or refractive power asymmetry) in civilians and in U.S. Army personnel. In nearsightedness, farsightedness or astigmatism, the clear front surface of your eye, the "cornea", does not have the proper focusing power. To correct this deficiency you must wear lenses, either glasses or contacts, either in front of the cornea or on the cornea in order to see clearly. Both LASIK and PRK use a machine called an excimer laser to reshape your cornea to try and give it the proper focusing power. In the LASIK procedure a "flap" is made in the cornea using another laser, called a femto-second laser. The flap is lifted and the excimer laser is used to reshape the cornea underneath. The flap is then replaced and allowed to heal. In the PRK procedure no flap is made. Instead, the outer layer of cells on the clear part of your eye, the corneal epithelium, is removed exposing the layer to be treated by the laser. Use of both lasers to make the flap and reshape the cornea is approved by the Food and Drug Administration (FDA) and the procedure is not considered investigational (experimental). These are the exact same procedures that other soldiers are receiving at WRAMC & NNMC and are considered 'standard of care.'

Both LASIK and PRK surgeries can be either wavefront guided or wavefront optimized. The wavefront guided procedure customizes the laser treatments based on the individual characteristics of the eye being corrected. The wavefront optimized procedure uses laser treatment software that has been designed with certain wavefront corrections pre-programmed, and a customized wavefront plan is not employed.

3. PROCEDURES TO BE FOLLOWED

This study will be conducted in three sequential phase. You will only be in a single phase. The phase you are in will depend upon when you agree to be in the study.

Phase I will consist of a preoperative evaluation and testing at WRAMC, the surgery either at WRAMC (wavefront optimized) or NNMC (wavefront guided), and post-operative evaluations at WRAMC. Phase I will consist of a total of 112 subjects.

Phase II will consist of a preoperative evaluation and testing at WRAMC, a pre-operative indoor M16 night fire range at Ft. Belvoir, the surgery either at WRAMC (wavefront optimized) or NNMC (wavefront guided), and post-operative evaluations at WRAMC and post-operative M16 night fire range at 6 wks and 6 mos. Your marksmanship skill will be evaluated with an M16-A2 rifle on a modified range under low light or nighttime conditions. The purposes of these tests are to evaluate the effect of the types of surgeries on night vision in a military environment. You will undergo testing in the night firing range at the Night Vision and Electronic Sensors Directorate at Ft. Belvoir a total of three times (before surgery, 6 weeks and 6 months after surgery). You will need to arrange your own transportation to Ft. Belvoir and this will result in some cost to you if you use a POV. Testing will be during normal business hours in a facility that simulates nighttime conditions. Phase II will consist of a total of 56 subjects.

Phase III will consist of a preoperative evaluation and testing at WRAMC, a pre-operative computer simulation at Ft. Belvoir requiring you to identify images of military vehicles at Ft. Belvoir, the surgery either at WRAMC (wavefront optimized) or NNMC (wavefront guided) post-operative evaluations at WRAMC and post-operative computer simulation requiring you to identify images of military vehicles at Ft. Belvoir. The training and testing you will receive will consist of identifying and recognizing thermal images of military vehicles displayed on a computer monitor. Vehicles will be at various resolutions and in different background environments, simulating real world nighttime conditions. Your responses will be scored and evaluated. The purposes of these tests are to evaluate the effect of the types of surgeries on night vision in a military environment. You will undergo testing in the Human Perception Laboratory at the Night Vision and Electronic Sensors Directorate at Ft. Belvoir a total of three times (before surgery, 6 weeks and 6 months after surgery). You will need to arrange your own transportation to Ft. Belvoir and this will result in some cost to you if you use a POV. You will also be required to pass a pretest each time before you can begin testing. The pretest will ascertain if you know the military vehicles well enough to undergo testing. If you do not pass the pre-test, you will not be allowed to test. Testing will be during normal business hours in a facility that simulates nighttime conditions. Phase III will consist of a total of 56 subjects.

All Phases

If you agree to be in this study you will be randomly assigned (similar to the flip of a coin) to receive either a wavefront optimized ablation pattern or a wavefront guided ablation pattern. You will NOT be randomly assigned either PRK or LASIK and that decision will be up to you and your doctor. Your

chances of being assigned to each group are equal. Depending on your assigned group, you will be treated at either the Walter Reed Army Medical Center Refractive Surgery Clinic or the NNMC at Bethesda. If you are receiving surgery at NNMC, you may drive directly to NNMC on the day of surgery, but depending on where you are traveling from, you may incur additional cost. For your convenience, you may park at WRAMC, take a shuttle bus to NNMC, undergo surgery, and return to WRAMC via the shuttle bus. The shuttle bus leaves every 30" on the hour and 1/2 hour in front of the main lobby on the first floor.

Demographic data, such as age and gender, will be collected during your screening exam in order to provide a correlation with clinical data. You will undergo eye testing before surgery and at 1, 3, 6 and 12 months after the surgical procedure at Walter Reed Army Medical Center as part of the standard of care (SOC). This will involve measuring vision, refraction (the need for glasses), eye pressure, corneal (the clear transparent outer layer of the eye) curvature, corneal clarity, corneal thickness, and contrast sensitivity [the ability to distinguish vertically oriented lines of different sizes and levels of contrast (e.g. black & white v. shades of gray)]. On several examinations, some of these tests will be repeated after your eyes have been dilated with eye drops.

As part of this study, you will be asked to undergo some additional eye testing for research purposes at the eye examination before surgery and at the examinations done 1, 3, 6, and 12 months after surgery. Your vision will be measured using standard visual acuity chart and 2 charts with low contrast letters (e.g. low contrast=faded, light grey letters). You will also be asked to complete a questionnaire before surgery and 1, 3, 6 and 12 months after surgery to determine your satisfaction with your laser eye surgery. It will take you approximately 5 minutes to complete the questionnaire each time it is given. A topographic (surface) map of your eye will be obtained using a Wavefront Analyzer. Contrast sensitivity will be measured using a computer, which displays spatial gratings (e.g. vertical stripes) on a monitor. The computer will vary the size of the vertical stripes and the level of contrast of the stripes (e.g. black & white v. shades of gray). Your task will be to identify which side of the monitor the spatial grating appears. This will take you approximately 20 minutes to complete. Each clinic appointment will last from one to two hours.

If you are a woman capable of having children, you will be asked to have a urine pregnancy test before the surgical procedure. If this test is positive, you will not be able to continue in this study. Additionally, if you plan to become pregnant in the next 12 months you can not be in this study since pregnancy has been shown to cause a change in the spectacle prescription.

In November 2005 the Base Closure and Realignment Commission (BRAC) designated the closure of Walter Reed Army Medical Center. Walter Reed Army Medical Center will be incorporated with the National Naval Medical Center to become the Walter Reed National Military Medical Center (WRNMMC) at Bethesda in September 2011. This study will continue with the same research team at the WRNMMC and/or FBCH. You will be informed by telephone of the move by a member of the research team prior to this occurring. The WRNMMC clinic can be reached at (301) 295-1133 and FBCH Clinic can be contacted at (703) 805-0193.

4. AMOUNT OF TIME FOR YOU TO COMPLETE THIS STUDY

You will be part of this study for slightly more than 12 months. The amount of time required to

complete this study will depend on which phase of the experiment you take part in.

Phase I, Phase II, and Phase III: During phase I, you will be asked to visit the WRAMC clinic up to 10 times. Additionally, if you are randomized to receive WFG surgery, you will have to go to the NNMC to receive surgery. You will be seen at WRAMC the day after surgery, 3 or 4 days after surgery, and one week after surgery. Each visit will last about 15 to 30 minutes. Additional follow-up evaluations will be at 1 month, 3 months, 6 months and 12 months following your surgery. These visits will last up to 1 to 2 hours each. Over the entire twelve months, this will require as much as 10 hours of examination time after the surgery (postoperatively). The standard amount of time for patients not involved in research is about eight hours. Research candidates can expect an additional two hours of testing.

Phase II: In addition to your follow-ups at WRAMC, you will be asked to fire an M16 at a range at Ft. Belvoir preoperatively, at 6 weeks post-operatively, and at 6 months post-operatively. You will not be asked to qualify at this range, but to shoot at a target located at variable distance from you location. This requirement is expected to take approximately 60 minutes. The standard amount of time for patients not involved in research is about eight hours. Research candidates in phase II can expect an additional 5 hours of testing.

Phase III: In addition to your follow-ups at WRAMC, you will be asked to visit the Night Vision Laboratories a total of 3 times (before surgery and at 6 weeks and 6 months after surgery) to participate in the night vision sensor testing. You will be provided training software to complete on your own. This will take approximately 4 hours. Prior to testing at Ft. Belvoir you will undergo refresher training that may last up to 4 hours, depending on your skill. The testing period will last up to 3 hours. Research subjects in Phase III can expect to expend an extra 21 hours of testing.

5. NUMBER OF PEOPLE THAT WILL TAKE PART IN THIS STUDY

There will a total of 224 people in total taking part in this study. A total of 112 will be enrolled in phase I, 56 patients will be in phase II, and 56 patients will be in phase III.

6. POSSIBLE RISKS OR DISCOMFORTS FROM BEING IN THIS STUDY

There are no significant risks that may develop as a result of participation in this study other than those associated with the surgery itself. Given that the surgery is NOT experimental and would be performed as standard of care outside of this research project, those risks are not addressed in the research consent form. The surgeon will discuss the risks associated with the surgery when you review the surgical consent form. None of the testing procedures pose any risk beyond a normal eye examination, viewing a computer monitor, or military training.

Any additional risks that may develop as a result of your participation in this study, other than those associated with the procedure itself are related to the M16-A3 night firing range. Military personnel trained in the use of night vision devices and small arms range activities will supervise all operations of this part of the study. Strict adherence to all range safety instructions will mitigate any risk of injury. The risks of injury are expected to be similar to those of any military supervised rifle range activity.

None of the contrast sensitivity (the ability to distinguish vertically oriented lines of different sizes and levels of contrast (e.g. black & white v. shades of gray)) testing or the night vision sensor testing has any risks other than those associated with looking at a computer monitor. However, because of the travel required to Ft. Belvoir in addition to the required pre-test training, Phase III has the largest time commitment of the three phases. This will be further discussed on the NVESD Informed consent. Additionally, you may incur additional costs associated with driving to Ft. Belvoir.

While all risks that we know about have been listed above, other risks about which we do not know may occur or be discovered during future studies. If we find that there was a major risk to you that was not known at the time of your participation in the study, and the risk might have some effect on your health, you will be informed.

7. POSSIBLE BENEFITS FROM BEING IN THIS STUDY

The information we gain from you being in will help us gain important knowledge regarding the visual performance of Soldiers who receive the wavefront optimized and wavefront guided surgery. This knowledge will assist us in providing the best possible refractive surgery procedures to future Soldiers.

8. CONFIDENTIALITY/PRIVACY OF YOUR IDENTITY AND YOUR RESEARCH RECORDS

The principal investigator will keep records of your being in this study. These records may be reviewed by individuals from the Walter Reed Department of Clinical Investigation (DCI), the Institutional Review Board and the Responsible Conduct of Research Service at the NNMC, the Walter Reed Human Use Committee (HUC), Human Research Protection Office (HRPO) of the U.S. Army Medical Research & Materiel Command (USAMRMC), the Army Clinical Investigation Regulatory Office (CIRO), and other government agencies as part of their duties. These duties include making sure that research subjects are protected. Collaborators of the study will not have access to your medical records. Confidentiality of your records will be protected to the extent possible under existing regulations and laws. Complete confidentiality cannot be promised, particularly for military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. Your name will not appear in any published paper or presentation related to this study.

When you enter this study you will be given a study ID number which will not contain any part of your social security number. This study ID number, not your name or social security number, will be used to label your data for analysis. However, because you are also a patient we will maintain your name and personal information in your study (paper) chart. This will assist us in prescribing you medication if you might need it. The randomization table linking your study ID number with your personal identifying information will be kept in a locked file in the Walter Reed Center for Refractive Surgery and after Walter Reed closes, at Fort Belvoir Army Community Hospital, Ft. Belvoir, VA, and access to it will be restricted to the principal investigator and his designee(s). All clinical and research data will be kept for 7 years.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA).

9. CONDITIONS UNDER WHICH YOUR PARTICIPATION IN THIS STUDY MAY BE STOPPED WITHOUT YOUR CONSENT

Your taking part in this study may be stopped without your consent if remaining in the study might be dangerous or harmful to you. Your taking part in this study may also be stopped without your consent if the military mission requires it, or if you become ineligible for medical care at military hospitals. The principal investigator may terminate your participation in this study if you fail to attend the baseline or follow-up examinations or elect not to undergo the laser procedure.

10. ELIGIBILITY AND PAYMENT FOR BEING IN THIS STUDY

You will not be paid for your participation in this research study.

11. COMPENSATION IF INJURED AND LIMITS TO MEDICAL CARE

Should you be injured as a direct result of being in this study, you will be provided medical care for that injury at no cost to you. You will not receive any compensation (payment) for injury. You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics). Necessary medical care does not include in-home care or nursing home care.

12. COSTS THAT MAY RESULT FROM TAKING PART IN THIS STUDY

There are no additional costs for taking part in this study other than returning to WRAMC for your follow-up appointments, driving to Ft. Belvoir, or lost duty time. Additionally, if your surgery is conducted at NNMC, you can either park at WRAMC on the day of surgery and take a government sponsored shuttle-bus (leaves on the half-hour) or you can drive directly to NNMC.

13. IF YOU DECIDE TO STOP TAKING PART IN THIS STUDY AND INSTRUCTIONS FOR STOPPING EARLY

You have the right to withdraw from this study at any time. If you decide to stop taking part in this study, you should tell the principal investigator as soon as possible. By leaving this study, you do not risk losing your right to medical care. Some testing or period of observation by the investigators may be recommended for you in order for you to safely stop taking part in this study. Any new significant finding during the course of this study that might affect your willingness to continue participation will be communicated to you.

14. STEPS TAKEN BEFORE AND DURING THIS STUDY TO PROTECT YOU

The surgery will be conducted according to manufacturer's guidelines and in the same way as it would be done if you were not taking part in this study. Additionally, we will follow the "standard of care" or "best clinical practices" in all preoperative and postoperative evaluations and you will be carefully monitored for complications of the surgery. Any undesired, clinically significant change in the eye or eyes operated on will be evaluated and treated by investigators.

To monitor for glaucoma, your intraocular pressure (pressure inside the eye) will be measured while you are taking topical steroid drops. We will use a technique called applanation tonometry with either a

tonopen or a Goldmann Applanation tonometry. These devices measure the pressure inside your eyes by gently touching the front of your eyes until a predetermined circular area is achieved. Your post-operative medications will be changed when necessary if your eye pressure is significantly increased.

If you are pregnant or if you plan to become pregnant, you will not be eligible for surgery. Women of child-bearing age must take a urine pregnancy test before starting this study. The order for the pregnancy test will be submitted during the preoperative evaluation. The pregnancy test must be completed by an accredited US Army Laboratory. You can either do it at the WRAMC lab which located down the hall from CRS or you can complete the test at the lab located at your home station. If this test is positive, you cannot take part in this study.

15. WHAT ARE THE UNKNOWN RISKS TO YOU OR AN UNBORN CHILD/FETUS

It is not known whether this treatment or the medication associated with the surgery might harm an unborn child. Therefore, you should not be in this study if you are pregnant. Also, you should not be in this study if you are breast-feeding since the medications may be passed from mother to child. A period of six month must elapse from the cessation of breast feeding before a soldier is eligible for refractive surgery. This is a requirement for ALL refractive surgery patients, not just refractive surgery patients. This is to ensure refractive stability has been achieved.

You should avoid becoming pregnant while you are taking part in this study as it has been shown that pregnancy can change a patient's spectacle prescription. If you plan to become pregnant during the study period, you are not eligible for surgery as a study subject. Please inform the research director and you may receive surgery as a regular patient. However, you should avoid becoming pregnant for at least six months after receiving the treatment. The reason for avoiding pregnancy for at least 6 months after the surgery is because of the possibility that re-treatment may be necessary

To avoid becoming pregnant you should either have no sexual relations or use a reliable type of birth control. Except for removal of the uterus (womb) for women and vasectomy (surgical cutting of the tubes that carry sperm) for men, birth control methods are not totally effective in preventing pregnancy. The only ways to completely avoid this risk of the treatment to an unborn baby are (1) avoid pregnancy, or (2) do not take this treatment.

16. OTHER PROCEDURES OR TREATMENTS THAT YOU COULD CHOOSE

You may choose to be treated for your nearsightedness without taking part in this study. Should you decide not to participate in this research study, you have the option of continuing to wear either glasses, contact lenses or have these procedures (or other refractive procedure) completed elsewhere. You may also choose to have PRK or LASIK done outside of this study. PRK and LASIK are done at Walter Reed as a standard of care procedures without participation in any research study. Surgical alternatives to PRK and LASIK include laser subepithelial keratectomy (LASEK) and epithelial LASIK (epi-LASIK), radial keratotomy and lens implants. Your doctor can provide you with more information about your nearsightedness, farsightedness and astigmatism and the benefits and risks of the different treatments available. You are encouraged to discuss this with your doctor.

17. IMPORTANT NEW FINDINGS THAT MAY AFFECT YOUR WILLINGNESS TO STAY IN THE STUDY

If we learn new information during the study that could affect your decision to be in this study, we will tell you this information. For example, if we learn about new severe side effects of the treatment, we will tell you about these side effects. The results of the research will be provided to you if you so desire.

18. YOUR RIGHTS IF YOU TAKE PART IN THIS STUDY

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care nor will it affect your military career status.

19. AUTHORIZATION FOR RESEARCH USE OF PROTECTED HEALTH INFORMATION

The Federal Health Insurance Portability and Accountability Act (**HIPAA**) includes a Privacy Rule that gives special safeguards to Protected Health Information (**PHI**) that is identifiable, in other words, can be directly linked to you (for example, by your name, Social Security Number, birth date, etc.). We are required to advise you how your PHI will be used.

(1) What information will be collected?

For this research study, we will be collecting information about your eye examinations, refractive surgery, eye health status, any side effects that you are experiencing, and how the treatment affects your comfort. These include vision, refraction (the need for glasses), eye pressure, corneal (the clear transparent outer layer of the eye) curvature, corneal clarity, corneal thickness, wavefront analysis, and contrast sensitivity (testing your vision under different dark to light contrast conditions). Some patients will have additional testing in night vision performance that will be also be collected. We will also be collecting your (PHI) such as your name, age, telephone, and fax numbers, email address and your social security number.

(2) Who may use your PHI within the Military Healthcare System?

The members of the Center for Refractive Surgery research team will have access to your health information in order to find out if you qualify to participate in this study, to plan and conduct your surgery, to administer research medication, to monitor your progress, and to analyze the research data. Additionally, your PHI may be made available to health oversight groups such as the WRAMC Department of Clinical Investigation and the WRAMC Institutional Review Board.

(3) What persons outside of the Military Healthcare System who are under the HIPAA requirements will receive your PHI?

No persons outside the Military Healthcare System will be sent your PHI.

(4) What is the purpose for using or disclosing your PHI?

Your protected health information will be collected and used during the course of the research

study, to monitor your health status, to measure the effects of drugs or devices or procedures, to determine research results, and to possibly develop new tests and procedures. The information may also be reviewed when the research study is audited for compliance. When the study is over, you have the right to see the information and copy it for your records.

(5) How long will the researchers keep your PHI?

The research team in the Center for Refractive Surgery will keep the research data for up to seven years after the end of the study. At the end of this time the data will be destroyed.

(6) Can you review your own research information?

Because the research includes blinding research participants to their study group, you will not be able to look at your research information until your participation in the study has ended.

(7) Can you cancel this Authorization?

Yes. If you cancel this Authorization, you will no longer be included in the research study. However, the information that has already been collected will be kept by the research team to assure patient safety. If you want to cancel your Authorization, please contact the Principal Investigator in writing. If you decide to participate in this research study, your Authorization for this study will not expire unless you revoke or cancel it in writing to the research doctor. If you revoke your Authorization, you will also be removed from the study, but standard medical care and any other benefit to which you are entitled will not be affected in any way.

(8) What will happen if you decide not to grant this Authorization?

If you decide not to sign this Authorization, you will not be able to participate in this research study. Refusal to sign this Authorization will not result in any loss of medical benefits to which you are otherwise entitled.

(9) Can your PHI be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?

There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your PHI include representatives of the Army Clinical Investigation Regulatory Office, the Food and Drug Administration, the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), and the DHHS Office for Civil Rights. This disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule.

(10) Who should you contact if you have any complaints?

If you believe your privacy rights have been violated, you may file a written complaint with

the WRAMC Privacy Officer, located at 6900 Georgia Ave., NW, Washington, DC 20307. Telephone: 202-782-3501.

Your signature at the end of this document acknowledges that you authorize WRAMC personnel to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.

20. CONTACTS FOR QUESTIONS ABOUT THE STUDY

If you have questions about the study, or if you think you have a study-related injury you should contact the principal investigator at 202-782-0202 (WRAMC), or after the BRAC at (301) 295-1133 (WRNMMC) or (703) 805-0193 (FBCH). For questions about your rights as a research participant, contact the Center Judge Advocate at 202-782-1550, Walter Reed Army Medical Center.

A copy of this consent form will be provided to you.

SIGNATURE OF RESEARCH SUBJECT

I have read the information in this consent form. I have been given a chance to ask questions and all of my questions have been answered to my satisfaction.

BY SIGNING THIS CONSENT FORM, YOU FREELY AGREE TO TAKE PART IN THE RESEARCH IT DESCRIBES.

_____ _____

Subject's Signature Date

_____

Subject's Printed Name

SIGNATURE OF INVESTIGATOR

I have explained the research to the volunteer, or his/her legal representative, and answered all of his/her questions. I believe that the volunteer/subject understands the information described in this document and freely consents to participate.

_____

Investigator's Signature Date (must be the same as the participant's)

_____

Investigator's Printed Name

DEPARTMENT OF THE NAVY
NATIONAL NAVAL MEDICAL CENTER
BETHESDA, MARYLAND 20889-5600

IN REPLY REFER TO
6500
14IV00/224
04 AUG 2010

From: Commander, National Naval Medical Center
To: CDR David Cute, MC, USN

Subj: REVIEW AND NOTATION OF A TEMPORARY MEDICAL MONITOR CHANGE FOR RESEARCH PROJECT NNMC.2009.0051, "OPTICAL QUALITY, THRESHOLD TARGET IDENTIFICATION, AND MILITARY TARGET TASK PERFORMANCE AFTER ADVANCED KERATOREFRACTIVE SURGERY"

Ref: (a) CDR D. Cute and COL K. Bower memo of 28 June 2010
(b) Curriculum vita for COL A. Eiseman, MC, USA
(c) IRB vice chair's IRBNet review of 20 July 2010

1. References (a) through (c) (temporary medical monitor change at NNMC to COL A. Eiseman from 10 September 2010 through 10 November 2010), reviewed by a vice chair of the NNMC IRB per reference (c), is noted.

2. Maintain complete records concerning this review and notation in the research project file.

3. Do not hesitate to contact the NNMC Responsible Conduct of Research Service staff at (301) 295-2275 or NNMC-ResearchQuestions@med.navy.mil for assistance.

J. T. LENERT
By direction

DEPARTMENT OF THE NAVY
NATIONAL NAVAL MEDICAL CENTER
BETHESDA, MARYLAND 20889-5600

IN REPLY REFER TO

6500
Ser 14IV00/121
FEB 07 2011

From: Commander, National Naval Medical Center
To: LTC M. Mines, MC, USA
CDR D. Cute, MC, USN

Subj: APPROVAL OF AMENDMENT #2 (INVESTIGATOR CHANGE) FOR RESEARCH PROJECT NNMC.2009.0051, "OPTICAL QUALITY, THRESHOLD TARGET IDENTIFICATION, AND MILITARY TARGET TASK PERFORMANCE AFTER ADVANCED KERATOREFRACTIVE"

Ref: (a) IRBNet submission of 7 Jan 11
(b) IRB Chair IRBNet endorsement of 15 Jan 11
(c) SECNAVINST 3900.39D

1. Reference (a), changing WRAMC principal investigator from COL K. Bower, MC, USA to LTC M. Mines, MC, USA as the new WRAMC principal investigator has been reviewed and recommended for approval, reference (b), under the provisions of 32 CFR 219.110 (b)(2) using reference (c), and is approved. This change to research project will be documented in the 10 February 2011 IRB meeting minutes.

2. Be sure to maintain complete records concerning this change with your original project file.

3. It is noted that CDR D. Cute will remain the NNMC principal investigator.

4. Please do not hesitate to contact the Responsible Conduct of Research Service (RCRS) staff at (301) 295-2275 for any assistance or concerns.

S. I. Gaines

S. I. GAINES
By direction

Copy to:
Research Coordinator
Study File
DON-HRPP
NNMC.2009.0051-AM2-EP9-A

DEPARTMENT OF THE NAVY
NATIONAL NAVAL MEDICAL CENTER
BETHESDA, MARYLAND 20889-5600

IN REPLY REFER TO

6500
Ser 14IV00/120
FEB 09 2011

From: Commander, National Naval Medical Center
To: LTC M. Mines, MC, USA
CDR D. Cute, MC, USN

Subj: APPROVAL OF AMENDMENT #3 (ENROLLMENT REQUEST ADDENDUM) FOR RESEARCH PROJECT NNMC.2009.0051, "OPTICAL QUALITY, THRESHOLD TARGET IDENTIFICATION, AND MILITARY TARGET TASK PERFORMANCE AFTER ADVANCED KERATOREFRACTIVE"

Ref: (a) IRBNet submission of 19 Jan 11
(b) IRB Chair IRBNet endorsement of 3 Feb 11
(c) SECNAVINST 3900.39D

1. Reference (a), request to proceed to Phase II and Phase III enrollment for the PRK group while continue to enroll LASIK patients in Phase I has been reviewed and recommended for approval, reference (b), under the provisions of 32 CFR 219.110 (b)(2) using reference (c), and is approved. These changes to research project will be documented in the 10 February 2011 IRB meeting minutes.

2. Be sure to maintain complete records concerning these changes with your original project file.

3. The NNMC deferred IRB review to the WRAMC IRB for this study, per the reciprocal IRB Authorization Agreement (IAA) between the NNMC and WRAMC.

4. Please do not hesitate to contact the Responsible Conduct of Research Service (RCRS) staff at (301) 295-2275 for any assistance or concerns.

S. I. GAINES
By direction

Copy to:
Research Coordinator
Study File
DON-HRPP
NNMC.2009.0051-AM3-EP9-A

DEPARTMENT OF THE NAVY
NATIONAL NAVAL MEDICAL CENTER
8901 WISCONSIN AVENUE
BETHESDA MARYLAND 20889-5600

IN REPLY REFER TO

6500
SER 14IV00/213
22 MAR 2011

From: Commander, National Naval Medical Center
To: CDR D. Cute, MC, USN

Subj: APPROVAL OF AMENDMENT #4 FOR RESEARCH PROJECT NNMC.2009.0051, "OPTICAL QUALITY, THRESHOLD TARGET IDENTIFCATION, AND MILITARY TARGET TASK PERFORMANCE AFTER ADVANCED KERATOREFRACTIVE SURGERY"

Ref: (a) Your memo submission on IRBNet [352274-7] of 24 Feb 11
(b) Vice IRB Chair IRBNet endorsement of 16 Mar 11
(c) SECNAVINST 3900.39D

1.Reference (a), the additions of L. Logan, OD, J. Pasternak, M.D., L. Peppers, Sia, M.D., and COL R. Stutzman, MC, USA as associate investigators has been reviewed and recommended for approval, reference (b), under the provisions of 32 CFR 219.110(b)(2) and reference (c), and is approved

2. This change to the research project will be documented in the 14 April 2011 IRB meeting minutes.

3. Be sure to maintain complete records concerning this change with your original project file.

4. Please do not hesitate to contact the Responsible Conduct of Research Service (RCRS) staff at (301) 295-2275 for any assistance or concerns.

S. I. Gaines
S. I. GAINES
By direction

Copy to:
DON-HRPP
NNMC.2009.0051.AM04.EP9-A

Appendix 2

Association for Research and Vision in Ophthalmology Meeting

Trudo and co-authors presented a pilot study on cadets seeking refractive surgery. Using the National Eye Institutes' Refractive quality of life survey of visual performance and satisfaction, the authors found out that with the subjects' current correction, clarity of vision, expectations, far vision activity limitation, worry, suboptimal correction, appearance and satisfaction with correction to be significantly less than normal. Scores for glare and dependence on correction were better than normal and near vision, diurnal fluctuations and symptoms were not different from normal.

Laser refractive surgery, like any surgery, may also face unintended side effects. In the study done by Fabrikant and associates, they found out that higher-order aberration may be induced mainly by changes in anterior corneal surface after laser refractive surgery. Bucay and co-authors presented a study determining changes in contrast sensitivity in myopic patients after LASIK surgery. Using Sine Wave Contrast test (SWCT), their study showed at 1 month postop, contrast sensitivity changes at medium to high spatial frequencies (6, 12 and 18 c/deg) were significantly different in high myopia but not in low myopia. These significant changes translate to increase discomfort in lower lighting conditions; patients may experience discomfort at night that may not be explained by induced aberrations of the optical system. With contrast sensitivity being altered at higher cycles, a higher intensity of light would be required to distinguish contrast among the perceived images. In the study done by Schallhorn and associates, patients who underwent wavefront-guided LASIK were assessed for satisfaction, level of disability with glare and halo symptoms and night driving difficulty post-operatively. They found out that preop refraction and postoperative uncorrected visual acuity to be significant predictors of both night glare and night halo complaints. Low light pupil size was not predictive of postop night problems.

References:

Edward W. Trudo, Jr., Susan Gromacki, Christopher Eastburg **Quality of Life in West Point Cadets Seeking Refractive Surgery**.

Anatoly Fabrikant, Dimitri Chernyak. **Analysis of Wavefront and Corneal Topography Changes due to Laser Refractive Surgery.**

Simon Romano-Bucay, Regina Velasco-Ramos, Oscar Baca-Lozada, Oscar Fernandez-Vizcaya, Alejandro Babayan-Sosa. **Determination Of Changes In Contrast Sensitivity In Myopic Patients With LASIK Surgery.**

Steven C. Schallhorn, Mitchell Brown **Relationship Between Mesopic Pupil Size and Symptoms in Myopic Patients After LASIK.**